

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT:** P. Baraldi  
**U.S.S.N.:** - **GROUP ART UNIT:** 1624 (presumed)  
**FILED:** Herewith **EXAMINER:** T. Truong (presumed)  
**FOR:** ALLOSTERIC ADENOSINE RECEPTOR MODULATORS

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**CERTIFICATE OF EXPRESS MAIL**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," Express Mail Label No. **EV342612850US** addressed to: **MAIL STOP PATENT APPLICATION**, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on

9.15.03

By:

Donna R. Davis

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**MAIL STOP PATENT APPLICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- a. \_\_\_\_\_ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. X \_\_\_\_\_ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application Serial No. 09/811,679, filed on March 19, 2001. The following references were submitted to, and/or cited by, the Office in the prior application (s) and, therefore, are not required to be provided in this application.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

- a. X \_\_\_\_\_ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
- b. \_\_\_\_\_ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. \_\_\_\_\_ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)  
(check one box)

- a. X \_\_\_\_\_ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1). No fee or certification is required.
- b. \_\_\_\_\_ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2). No fee or certification is required.

- c. \_\_\_\_\_ Before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. \_\_\_\_\_ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).  
or  
b. \_\_\_\_\_ See the certification below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. \_\_\_\_\_ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or  
b. \_\_\_\_\_ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

Attorney Docket No.: 57458-CIP2-C

P. Baraldi

U.S.S.N.: -

Filing Date: Herewith

Group Art Unit: 1624 (Presumed)

Examiner: T. Truong (Presumed)

c. \_\_\_\_\_ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

\_\_\_\_\_ Please charge Deposit Account No. 04-1105 in the amount of \$180.00 for the above-indicated fee. A triplicate copy of this paper is attached.

X \_\_\_\_\_ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule, with a petition if necessary, and charge the appropriate fee to Deposit Account No. **04-1105**.

Respectfully submitted,

Date: \_\_\_\_\_

9/15/03

By: \_\_\_\_\_

Gregory B. Butler

Gregory B. Butler, Ph.D., Esq.

Reg. No.: 34,558

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# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)

57458-CIP2-C(46453)

Application Number

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Applicant(s)

P. BARALDI

Filing Date

HEREWITH

Group Art Unit

1624 (PRESUMED)

## U.S. PATENT DOCUMENTS

| *EXAMINER<br>INITIAL | REF | DOCUMENT NUMBER | DATE    | NAME          | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|-----|-----------------|---------|---------------|-------|----------|-------------------------------|
|                      | AA  | 5,532,233       | 07/1996 | WEBER, ET AL. | 514   | 219      |                               |
|                      | AB  | 6,046,189       | 04/2000 | SOHDA, ET AL. | 514   | 217.07   |                               |
|                      |     |                 |         |               |       |          |                               |
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## FOREIGN PATENT DOCUMENTS

|  | REF | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | Translation |    |
|--|-----|-----------------|------|---------|-------|----------|-------------|----|
|  |     |                 |      |         |       |          | YES         | NO |
|  |     |                 |      |         |       |          |             |    |
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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| CA | DAVE, ET AL., "REACTION OF NITRITES UNDER ACIDIC CONDITIONS. PART I" JOURNAL OF HETEROCYCLIC CHEMISTRY, NOVEMBER 1980, VOL. 17, NO. 7 PP. 1497-1500.              |
| CB | BARALDI, ET AL., "SYNTHESIS AND BIOLOGICAL EFFECTS OF A NEW SERIES...." BIOORGANIC & MEDICINAL CHEMISTRY LETTERS, SEPTEMBER 2000, VOL. 10, NO. 17, PP. 1953-1957. |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|---|---|--|
| <b>FORM PTO-1449</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT</b> | <b>DOCKET NO.:</b><br><br>57458-CIP2-C(46453) | <b>SERIAL NO.:</b><br><br>-              |
|   | <b>APPLICANT(S):</b><br><br>P. Baraldi        |  |
|   | <b>FILING DATE:</b><br><br>HEREWITH           | <b>GROUP NO.:</b><br><br>1624 (PRESUMED) |

**UNITED STATES PATENT DOCUMENTS**

| EXAM.<br>INITIALS |    | DOCUMENT<br>NUMBER | DATE     | NAME    | CLASS | SUB-<br>CLASS | FILING DATE<br>IF<br>APPROPRIATE |
|-------------------|----|--------------------|----------|---------|-------|---------------|----------------------------------|
|                   | AA | US 6,177,444 B1    | 01/23/01 | Baraldi | 514   | 301           | 05/07/99                         |
|                   |    |                    |          |         |       |               |                                  |

**FOREIGN PATENT DOCUMENTS**

|  |  | DOCUMENT<br>NUMBER | DATE | COUNTRY | CLASS | SUB-<br>CLASS | TRANSLATION<br>YES/NO |
|--|--|--------------------|------|---------|-------|---------------|-----------------------|
|  |  |                    |      |         |       |               |                       |
|  |  |                    |      |         |       |               |                       |

**OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)**

|  |    |   |
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|  | CA | Copy of International Search Report dated 06 August 2003, issued in corresponding PCT Appl. No. PCT/US02/08821, filed 3/19/02.  |
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|-------------------|----|--------------------|----------|-------------------|-------|---------------|----------------------------------|
|                   | AA | US 6,323,214 B1    | 11/27/01 | Baraldi           | 514   | 301           |                                  |
|                   | AB | US 6,194,449 B1    | 02/27/01 | Baraldi           | 514   | 447           |                                  |
|                   | AC | 5,939,432          | 08/17/99 | Baraldi           | 514   | 301           |                                  |
|                   | AD | 5,585,385          | 12/17/96 | Natsugari, et al. | 514   | 300           |                                  |
|                   | AE | 5,026,698          | 06/1998  | Fujikawa, et al.  |       |               |                                  |
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**FOREIGN PATENT DOCUMENTS**

|  |    | DOCUMENT<br>NUMBER | DATE    | COUNTRY | CLASS | SUB-<br>CLASS | TRANSLATION<br>YES/NO |
|--|----|--------------------|---------|---------|-------|---------------|-----------------------|
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|  | BB | 3,724,031          | 01/1998 | GERMANY |       |               |                       |
|  | BC | 96/14319           | 05/1996 | PCT     |       |               |                       |
|  | BD | 5,345,785          | 12/1993 | JAPAN   |       |               |                       |
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|  | BF | 7,304,755          | 11/1995 | JAPAN   |       |               |                       |
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|  | BH | 393,101            | 05/1974 | SPAIN   |       |               |                       |
|  | BI | 2,323,149          | 11/1973 | GERMANY |       |               |                       |
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|--|--|---|-----------------------------------|
| <b>INFORMATION DISCLOSURE CITATION</b><br><i>(Use several sheets if necessary)</i> |  | Docket Number (Optional)<br>57458-CIPZ-C(46453) | Application Number                |
|  |  | Applicant(s)<br>BARALDI                         |                                   |
|  |  | Filing Date<br>HEREWITH                         | Group Art Unit<br>1624 (PRESUMED) |

  

| *EXAMINER<br>INITIAL | OTHER DOCUMENTS | (Including Author, Title, Date, Pertinent Pages, Etc.)   |
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|                      | CB              | CAS FOR ROUTH, ET AL., "TACHYKININ RECEPTORS IN THE SPINAL CORD, PROGRESS IN BRAIN RESEARCH," VOL. 104, PP 93-108.   |
|                      | CC              | CAS FOR CHESSELET, ET AL., "ISCHEMIC DAMAGE IN THE STRIATUM OF ADULT GERBILS: RELATIVE SPARING OF SOMATOSTATINERGIC AND CHOLINERGIC INTERNEURONS CONTRASTS WITH LOSS OF Efferent NEURONS," EXPERIMENTAL NEUROLOGY, VOL. 110, NO. 2, PP 209-218.                      |
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|                      | CF              | CAS FOR GHIO, ET., "CLINICAL EVALUATION OF CALCIUM-ANTAGONIST DRUGS," J OF CARDIOVASCULAR PHARMACOLOGY, VOL. 20, PP 571-74.  |
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|                      | CH              | CAS FOR UENO, ET AL., "SIMULTANEOUS DETERMINATION OF A NEW DIHYDROPYRIDINE CALCIUM BLOCKER AND ITS PYRIDINE METABOLITE IN DOG PLASMA BY COLUMN SWITCHING HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY WITH ELECTROCHEMICAL AND ULTRAVIOLET DETECTION," ANALYTICAL SCIENCE. |
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|                      | CK              | LEUNG, ET AL., "ENHANCEMENT OF ADENOSINE A1 RECEPTOR FUNCTIONS BY BENZOYLTHIOPHENES IN GUINEA PIG TISSUES IN VITRO," ARCHIVES OF PHARMACOLOGY, VOL. 352, NO. 2, PP 206-212.  |
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| EXAMINER | DATE CONSIDERED |
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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| <b>INFORMATION DISCLOSURE CITATION</b><br><i>(Use several sheets if necessary)</i>   |   | Docket Number (Optional)<br>57458-CIP2-C(46453)  |  | Application Number                |
|  |   | Applicant(s)<br>BARALDI  |  |                                   |
|  |   | Filing Date<br>HEREWITH  |  | Group Art Unit<br>1624 (PRESUMED) |
|  |   |  |  |                                   |
| *EXAMINER<br>INITIAL   | OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i> |  |  |                                   |
|  | CM  | MUDUMBI, ET AL., "CARDIA FUNCTIONAL RESPONSES TO ADENOSINE BY PD 81, 723, AN ALLOSTERIC ENHANCER OF THE ADENOSINE A1 RECEPTOR," AMERICAN JOURNAL OF PHYSIOLOGY, VOL. 264, PP H1017-H1022.  |  |                                   |
|  | CN  | NAKANISHI, ET AL., "STUDIES ON PSYCHOTROPIC DRUGS. 18.1 SYNTHESIS AND STRUCTURE-ACTIVITY RELATIONSHIPS OF 5-PHENYL-1,3-DIHYDRO-2H-THIENO[2,3-E][1,4] DIAZEPIN-2-ONES," JOURNAL OF MEDICINAL CHEMISTRY, VOL. 16, NO. 3, PP 214-219, 1973.               |  |                                   |
|  | CO  | ROBBA, ET AL., "NO. 144-THIENOPYRIMIDINES. IX - ETUDE DE LA THIENO[2,3-D]PYRIMIDINES ET DE SES DERIVES," BULETINE DE LA SOCIETE CHIMIQUE DE FRANCE, PP 761-764 (1976).   |  |                                   |
|  | CP  | AMOAH-APRAKU, ET AL., "SELECTIVE POTENTIATION BY AN A1 ADENOSINE RECEPTOR ENHANCER OF THE NEGATIVE DROMOTROPIC ACTION OF ADENOSINE IN THE GUINEA PIG HEART," THE JOURNAL OF PHARM. AND EXPERIMENTAL THERAPEUTICS, VOL. 266, NO. 2, P P 611-617 (1993). |  |                                   |
|  | CQ  | BHATTACHARYA, ET AL., "EFFECTS OF LONG-TERM TREATMENT WITH THE ALLOSTERIC ENHANCER, PD 81, 723, N CHINESE HAMSTER OVARY CELLS EXPRESSING RECOMBINANT HUMAN A1 ADENOSINE RECEPTORS," MOLECULAR PHARM., VOL. 50, PP 104-111 (1996).                      |  |                                   |
|  | CR  | BHATTACHARYA, ET AL., "THE ALLOSTERIC ENHANCER, PD 81, 723, STABILIZES HUMAN A1 ADENOSINE RECEPTOR COUPLING TO G PROTEINS," BIOCHIMICA ET BIOPHYSICS ACTA, 1265: PP 15-21, 1995.   |  |                                   |
|  | CS  | BRUNS, ET AL., "ALLOSTERIC ENHANCEMENT OF ADENOSINE A1 RECEPTOR BINDING AND FUNCTION BY 2-AMINO-3-BENZOYLTHIOPHENES," MOLECULAR PHARM., VOL 38, NO. 6, PP 939-949 (1990).  |  |                                   |
|  | CT  | BRUNS, ET AL., "STRUCTURE-ACTIVITY RELATIONSHIPS FOR ENHANCEMENT OF ADENOSINE A1 RECEPTOR BINDING BY 2-AMINO-3-BENZOYLTHIOPHENES," MOLECULAR PHARM., VOL 38, PP 950-958 (1990).  |  |                                   |
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|  | CV  | DENNIS, ET AL., "MODULATION OF ATRIOVENTRICULAR NODAL FUNCTION BY METABOLIC AND ALLOSTERIC REGULATORS ENDOGENOUS ADENOSINE IN GUINEA PIG HEART," CIRCULATION, VOL. 94, NO. 10, PP 2551-2559 (1996).  |  |                                   |
|  | CW  | FORTEA, "THIENO[2,3-D]PYRIMIDINE-3-OXIDES. SYNTHESIS AND N-OXIDE REACTIONS OF 4-PHENYL-AND-4-AMINO-THIENO[2,3-D]PYRIMIDINE-3-OXIDES," JOURNAL FUR PRAKTISCHE CHEMIE, BAND 317, HEFT 5, PP 705-711 (1975).  |  |                                   |
|  | CX  | HROMATKA, ET AL., UBER DIE NITRIERUNG VON 7-CHLOR-5-PHENYL-1H-THIENO[2,3-E][1,4-DIAZEPIN-2(3H)-ON," MONATSHEFT FUR CHEMIE, VOL. 104, PP 709-714 (1973).  |  |                                   |
| EXAMINER   |   | DATE CONSIDERED  |  |                                   |
| <p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance or not considered. Include copy of this form with next communication to applicant.</p> |   |  |  |                                   |

# **INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Docket Number (Optional)

57458-CIP2-C(46453)

Application Number

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Applicant(s)

BARALDI

Filing Date

HEREWITH

Group Art Unit

1624 (PRESUMED)

\*EXAMINER  
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CY

"JANUSZ, ET AL., "FUNCTIONAL ACTIVITY OF THE ADENOSINE BINDING ENHANCER, PD 81,723, IN THE IN VITRO HIPPOCAMPAL SLICE," BRAIN RESEARCH, VOL. 567, PP 181-187, (1991).

CZ

KOLLIAS-BAKER, ET AL., "NOVEL APPROACH FOR ENHANCING ATRIOVENTRICULAR NODAL CONDUCTION DELAY MEDIATED BY ENDOGENOUS ADENOSINE," CIR. RESEARCH, VOL. 75, NO. 6, PP 972-980 (1994).

EXAMINER

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